

Appl. No. 10/041,845  
Amdt. dated September 22, 2004  
Reply to Office Action of August 24, 2004

REMARKS

**I. Status of the Claims**

Claims 1-35 were originally filed, among which claims 11 and 22-30 have been canceled. Claims 35-43 have been added. Claims 1-10, 12-21, and 31-43 are currently pending.

**II. Claim Rejections**

**A. 35 U.S.C. §102**

Claims 17, 31, 32, and 37-40 was rejected under 35 U.S.C. §102(e) for alleged anticipation by Sharma (US 2003/0087394). Specifically, the Examiner stated that Sharma teaches a method for treating a subject having an insulin related disease, using a cell that is introduced to produce insulin. The Examiner further stated that Sharma teaches using human pancreatic  $\beta$ -cells, such as pancreatic endocrine cells, to produce such insulin-producing cells, which may be genetically modified to express one or more genes including both PDX-1 and NeuroD/BETA2, and further cultured in an environment where a certain level of cell-cell contact exists.

Applicants respectfully traverse the rejection. Sharma is a U.S. patent application that was filed August 30, 2002, and claims priority to provisional application USSN 60/316,453, filed August 31, 2001. A careful review of the contents of USSN 60/316,453 indicates, however, that the material the Examiner cited from Sharma is not present in the provisional application. As such, Applicants submit that this cited material in Sharma is entitled to only the actual filing date of August 30, 2002, but not the filing date of USSN 60/316,453, August 31, 2001. Since the present application was filed October 18, 2001, Sharma is not a §102(e) reference as far as the cited material is concerned.

The withdrawal of the anticipation rejection is respectfully requested.

**B. 35 U.S.C. §103**

Claims 1-10, 12-15, 17-21, and 31-43 were rejected under 35 U.S.C. §103(a) for alleged obviousness over Sharma in view of Levine (U.S. Patent No. 6,448,045). Specifically,

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the Examiner cited Sharma as a §102(e) reference for the same purpose as described in the last section and cited Levine as a reference to supply certain claim limitations that are not provided by Sharma, such as contacting human endocrine pancreatic -cell recombinantly expressing PDX-1 and NeuroD/BETA1 with a GLP-1 agonist, co-expression of one or more recombinant oncogenes in these cells, or co-expression of a telomerase gene in the cells.

Applicants respectfully traverse the rejection. As established in the last section, Sharma is not a §102(e) references against the present application, at least for the material cited by the Examiner; on the other hand, Levine does not provide all limitations of the pending claims. Accordingly, Applicants submit that no *prima facie* obviousness has been established.

The withdrawal of the obviousness rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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